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Biocon Biologics, Viatris receive US FDA approval for Semglee to treat diabetes

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Biocon Biologics and Viatris announced that the US Food and Drug Administration (FDA) has approved Semglee (insulin glargine-yfgn injection) as the first interchangeable biosimilar product under the 351(k) regulatory pathway.

Biocon Biologics, Executive Chairperson, Kiran Mazumdar-Shaw said, “We are proud to be the first to obtain approval of an interchangeable Biosimilar product in the US. It is a milestone achievement for both Biocon Biologics and our partner Viatris. This will allow pharmacy level substitution and thereby provide convenient and affordable access to Semglee, a quality Biosimilar Insulin Glargine.”

Arun Chandavarkar, MD, Biocon Biologics said, “This interchangeability approval for Semglee by the US FDA, another first to our credit, is a testament to our scientific excellence and robust quality comparability data. This allows substitution at the pharmacy counter, thus expanding patient access and sets the stage for future approvals for our other insulin products.”

The interchangeable Semglee product, which will allow substitution of Semglee for the reference product, Lantus, at the pharmacy counter, will be introduced before the end of the year. The company is eligible to have exclusivity for 12 months before the FDA can approve another biosimilar interchangeable to Lantus. Commercial preparations for launch are underway. Over the next few months, Viatris will transition the current product to the 351(k) interchangeable product.

Semglee is indicated to control high blood sugar in adults with Type 2 diabetes and adults and pediatric patients with Type 1 diabetes. It is not recommended for the treatment of diabetic ketoacidosis. Semglee has an identical amino acid sequence to Lantus and is approved for the same indications.

Michael Goettler, CEO, Viatris commented, “We are proud to achieve the industry’s first approval of an interchangeable biosimilar product in the US, which will help broaden access to this important diabetes medicine for patients, physicians, payers and providers. This is yet another important milestone for our company that not only continues to underscore the strength of our internal scientific capabilities but also supports our belief in the promising future of our company as we continue to work to identify innovative ways to increase access to complex treatments for patients.”

Rajiv Malik, President, Viatris added, “We are pleased to have once again worked with the FDA to achieve the very historic approval of the first interchangeable biosimilar in the US and are grateful to our partner, Biocon Biologics, for their collaboration in achieving this milestone."